



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
1401 Rockville Pike  
Rockville MD 20852-1448

Our STN: BL 103792/5004

DEC 11 2001

Robert L. Garnick, Ph.D.  
Genentech Incorporated  
1 DNA Way, MS #48  
South San Francisco, CA 94080

Dear Dr. Garnick:

Your request to supplement your biologics license application for Trastuzumab to revise the package insert to include updated median survival data has been approved.

Please submit all **final** printed labeling at the time of use and include implementation information on FDA Form 2567. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

This information will be included in your biologics license application file.

Sincerely yours,

*Patricia Keegan for Dr. Weiss*

Karen D. Weiss, M.D.  
Director  
Division of Clinical Trial Design  
and Analysis  
Office of Therapeutics  
Research and Review  
Center for Biologics  
Evaluation and Research